



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/763,567

01/23/2004

Rudolf Gilmanshin

C0989.70045US01

4885

7590

05/26/2006

Maria A. Trevisan
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210

EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|--|--|
| Office Action Summary | Application No. 10/763,567 | Applicant(s) GILMANSHIN ET AL. | |
| | Examiner Karlheinz R. Skowronek | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Species Election

1. Claims 1-6, 9-11, 14-15, 24-36, 39-43, 46, 48-49, 50-51 and 53-54 are generic to a plurality of disclosed patentably distinct species comprising:

Applicant is required under 35 U.S.C. 121 to elect 5 species consisting of a single labeled probe from group A, a single nucleic acid from group B, a single profile type from group C, a single polymer state from group D and a single intensity profile from group E as listed and recited below, even though this requirement is traversed.

- A. i) A specific labeled probe corresponding to a sequence specific label as recited in claims 7 and 16;
- A. ii) A specific labeled probe corresponding to a sequence non-specific labeled probe as recited in claims 8,17 and 47;
- B. i) A specific nucleic acid corresponding to genomic DNA as recited in claim 12;
- B. ii) A specific nucleic acid corresponding to mitochondrial DNA as recited in claim12;
- B. iii) A specific nucleic acid corresponding to cDNA as recited in claim 12;
- B. iv) A specific nucleic acid corresponding to mRNA as recited in claim 13;

Art Unit: 1631

- C. i) A specific profile type corresponding to cumulative as recited in claims 20, 22, and 37;
- C. ii) A specific profile type corresponding to average as recited in claims 21, 23, and 38;
- D. i) A specific polymer state corresponding to completely stretched as recited in claim 44;
- D. ii) A specific polymer state corresponding to partially stretched as recited in claim 45;
- D. iii) A specific polymer state corresponding to uniformly stretched as recited in claim 52;
- E. i) A specific intensity profile corresponding to being obtained from polymers in flow as recited in claim 18;
- E. ii) A specific intensity profile corresponding to being obtained from polymers fixed to a solid support as recited in claim 19.

The species within each group are distinct from each other because they have identifiably distinct functions, in the case of the labeled probes of group A, have identifiably distinct structures, in the case of the nucleic acids of group B, have identifiably distinct methods of calculation, in the case of the profile types of group C, have identifiably distinct states, in the case of the polymer states of group D, and are obtained from distinct locations, in the case of group E. Additionally the species of any

Art Unit: 1631

one group are distinct from those of any other group. For example, the species of group A, directed to distinct functions, are independent from those of Group B, directed to nucleic acids, those of group C, directed to results of distinct calculations, those of group D, directed to distinct physical states, and those of group E, directed to distinct locations. The species of group B directed to nucleic acids, are independent from those of group C, directed to results of distinct calculations, those of group D, directed to distinct physical states, and those of group E, directed to distinct locations. The species of group C, directed to results of distinct calculations, are independent from those of group D, directed to distinct physical states, and those of group E, directed to distinct locations. The species of group D, directed to distinct physical states, are independent from those of group E, directed to distinct locations.

Because these species are distinct for the reasons given above, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, species election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

Art Unit: 1631

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

